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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,105	07/02/2003	O Hasa Rastelli	21402-018DIV (Cura-318DIV	4239
75	90 08/28/2006		EXAM	INER
Jenell Lawson		SEP 1000	WOLLENBERG	GER, LOUIS V
Intellectual Prop 555 Long Whar	oerty CuraGen Corporatio f Drive	n 3EP 1.9 2006	ART UNIT	PAPER NUMBER
New Haven, C		A STATE OF THE STA	1635	
		OPMARIN	DATE MAILED: 08/28/2000	5

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)			
	10/613,105	RASTELLI ET AL.			
Office Action Summary	Examiner	Art Unit			
	Louis V. Wollenberger	1635			
The MAILING DATE of this communication ap Period for Reply	ppears on the cover sheet with the	e correspondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING IT Extensions of time may be available under the provisions of 37 CFR 1 after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period Failure to reply within the set or extended period for reply will, by statu Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMMUNICATION  .136(a). In no event, however, may a reply be  d will apply and will expire SIX (6) MONTHS fro  the cause the application to become ABANDO	ON. timely filed om the mailing date of this communication. NED (35 U.S.C. § 133).			
Status					
1) Responsive to communication(s) filed on 28	<u>June 2006</u> .				
	is action is non-final.				
3) Since this application is in condition for allow	ance except for formal matters, p	prosecution as to the merits is			
closed in accordance with the practice under					
Disposition of Claims					
4) Claim(s) 1-6,9 and 10 is/are pending in the a	pplication.				
4a) Of the above claim(s) is/are withdr					
5) Claim(s) is/are allowed.					
6)⊠ Claim(s) <u>1-6,9 and 10</u> is/are rejected.					
7) Claim(s) is/are objected to.					
8) Claim(s) are subject to restriction and	or election requirement.				
Application Papers					
9)☐ The specification is objected to by the Examir	ner.				
10) ☐ The drawing(s) filed on is/are: a) ☐ ac					
Applicant may not request that any objection to the					
Replacement drawing sheet(s) including the corre					
11) The oath or declaration is objected to by the	Examiner. Note the attached Offi	ice Action or form PTO-152.			
Priority under 35 U.S.C. § 119					
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:  1. Certified copies of the priority docume 2. Certified copies of the priority docume 3. Copies of the certified copies of the priority	nts have been received. nts have been received in Applic iority documents have been rece	cation No			
application from the International Bureau (PCT Rule 17.2(a)).					
* See the attached detailed Office action for a li	st of the certified copies not rece	ivea.			
Attachment(s)	<u></u>				
1) Notice of References Cited (PTO-892)	4) Interview Summ Paper No(s)/Mai				
Notice of Draftsperson's Patent Drawing Review (PTO-948)     Information Disclosure Statement(s) (PTO-1449 or PTO/SB/0 Paper No(s)/Mail Date		al Patent Application (PTO-152)			

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## **DETAILED ACTION**

## Location of the Application

The location of the application has changed. The application has been docketed to Examiner Louis V. Wollenberger in Art Unit 1635.

# Status of Application/Amendment/Claims

Applicant's response filed 6/28/2006 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 2/28/2006 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

With entry of the amendment filed on 6/28/2006, claims 1-6 and new claims 9 and 10 are pending and currently under examination.

## Claim Rejections - 35 USC § 102

Claims 1-6, 9, and 10 remain rejected under 35 U.S.C. 102(e) as being anticipated by Au-Young et al. (US 6,500,938). The invention set forth in claims 1-6 is relied upon as above. The invention set forth in claims 7 and 8 is drawn to the method above wherein the nucleic acid comprises SEQ ID NO: 1 or wherein the nucleic acid encoding an antileukoprotease polypeptide comprises the amino acid sequence of SEQ ID NO: 2.

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Applicants argue that Au-Young et al. do not specifically teach using instant SEQ ID NO:1 or sequences encoding SEQ ID NO:2 to identify colon, thyroid, or renal cancer.

However, it is the Examiner's position that the amendment to the preambles of claims 1 and 4 does not result in a manipulative difference between the claimed invention and the prior art (MPEP 2111.02). While applicants point to the amendments to the preamble to distinguish over the applied prior art, applicants are advised that the steps themselves do not reflect this limitation inasmuch as they continue to read on steps for measuring expression in a test sample and identifying the presence of a cancer cell. Therefore, the steps are not limited to a subset of cancer cell samples.

While Applicants have amended the preambles of independent claims 1 and 4 to recite methods for identifying colon, thyroid, and renal cancer cells, the preamble itself does not impose a material limitation on the steps themselves, which recite measuring the expression of a nucleic acid....in a test sample"; comparing the expression of the nucleic acid...."; wherein...indicates the presence of a cancer cell."

Thus, the claims remain broad, encompassing methods for measuring the expression of SEQ ID NO:1 or any nucleic acid encoding SEQ ID NO:2 in any test sample from any species (step a) and, in the case of claim 1, identifying any cancer cell in any test sample from any species by the measurement of "a comparable level of expression of" a "reference nucleic acid." Claims 1 and 4 conclude with a "wherein" phrase for identifying the presence of any cancer cell."

While the preambles of claims 1 and 4 set forth an intended or suggested use, they do not specifically limit the claimed methods to the analysis of colon, thyroid, or renal tissue-derived

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test samples. That is the preambles of claims 1 and 4 do not result in a manipulative difference between the claimed invention and the prior art. (MPEP 2111.02). The recited process steps are not limited to colon, thyroid, or renal cancer cell test samples and the "wherein" phrase that concludes each claim clearly recites "a cancer cell" not a colon, thyroid, or renal cancer cell.

If the prior art structure is capable of performing the intended use, then it meets the claim.

A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See In re Hirao, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and Kropa v. Robie, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

In Table 1, columns 65-66, Au-Young et al. disclose SEQ ID NO: 1271, said to represent a human mRNA sequence from the cervix/uterus. SEQ ID NO:1271 is 594 nucleotides in length and is identical to instant SEQ ID NO:1 (see the alignment in Exhibit A: Result 1 of STIC-Biotech sequence search of SEQ ID NO:1, issued patents database). Similarly, SEQ ID NO:1271 encodes a polypeptide comprising instant SEQ ID NO:2 (see Exhibit B: Result 1 of STIC-Biotech sequence search of SEQ ID NO:2, issued patents database).

Au-Young et al. disclose that the sequences of their invention can be used on a microarray or as hybridization probes in methods of expression profiling, in order to catalogue differences in gene expression between healthy and diseased tissues or cells (col. 11). Au-Young et al. disclose the use of expression profiling to diagnose cancer, including ovarian cancer (cols. 11-12). The disclosures of Au-Young et al. are reasonably considered to anticipate the instantly

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claimed invention because they disclose nucleic acid expression profiles that can be generated with the hybridization probe of their invention, including SEQ ID NO: 1271 would be compared, inherently, from healthy and diseased tissues or cells, in order to catalogue differences in gene expression and to diagnose cancer including ovarian cancer.

Therefore, Au-Young et al. anticipate the instant invention as set forth in claims 1-6, 9, and 10.

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Claims 1-6, 9, and 10 remain rejected under 35 U.S.C. 102(e) as being anticipated by Morin et al. (US 2003/0211498) (which claims priority from US Provisional Application 60/194,336).

Applicants' argue that Morin et al. do not teach the use of instant SEQ ID NO:1 or sequences encoding SEQ ID NO:2 to identify colon, thyroid, or renal cancer. However, the steps recited in the instant claims are not limited to detection of colon, thyroid, or renal cancer for the reasons given above.

Morin et al. disclose methods of detecting ovarian cancer in a subject by comparison of the expression of tumor marker genes between samples taken from the subject and normal and cancer reference profiles (pg. 1, [0005-0013). Morin et al. disclose SEQ ID NO: 53 that is an ovarian cancer tumor marker that is identical to instantly claimed SEQ ID NO: 1, that is the mRNA encoding secretory leukocyte protease inhibitor (which is also known as antileukoprotease) (pg. 2, [0023]; pg. 4, [0053]) (see also, attached sequence alignment, provided with previous Office Action).

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Therefore, Morin et al. anticipate the instant invention as set forth in claims 1-6, 9, and 10.

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# New Ground of Rejection Necessitated by Applicants' Amendments

# Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1–6 are rejected under 35 U.S.C. 102(e) as being anticipated by Gould-Rothberg et al. (US Patent 6,436,642).

Gould-Rothberg et al. teach that human antileukoprotease, GenBank Accession No. X04470, is expressed in colorectal carcinomas and is up-regulated in metastatic vs. non-metastatic thyroid cancer (column 15, line 63, to column 16, line 10; see also column 2, lines 5-25). At column 26, under General Screening and Diagnostic Methods, Gould-Rothberg et al. teach the detection and analysis of human antileukoprotease for diagnosing the presence and stage of thyroid cancer, and, presumably, other cancers in which human antileukoprotease is expressed. Gould-Rothberg et al. teach that the expression level of one or more of the disclosed metastatic thyroid carcinoma nucleic acid sequences (MTCs) in a test cell population is

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compared to expression levels of the sequences in one or more cells from a reference cell population. A reference cell population may comprise cancerous or non-cancerous cells, as required (column 26-27). Gould-Rothberg et al. teach that the test cell population may be known to contain or be suspected of containing a neoplasm. In some embodiments, the test cell will be included in a cell sample known to contain or suspected of containing a thyroid follicular adenoma (column 27, line 25-30).

Accordingly, Gould-Rothberg et al. teach the detection of human antileukoprotease, GenBank Accession No. X04470, for the detection and/or identification of thyroid cancer cells in a test sample. Gould-Rothberg et al. also appear to recognize and suggest the association of human antileukoprotease expression in colorectal cancers, and describe methods of detection that are generally applicable to the measurement of mRNA expression in any cancer cell population.

The instant application discloses that instantly recited SEQ ID NO:1 (claims 1 and 4) is identical to GenBank Accession No. X04470 (see page 2 of 60/207104 and page 18 of the instant application). Accordingly, Gould-Rothberg et al. teach a method for measuring and comparing the expression of instant SEQ ID NO:1 relative to a reference cell population, normal or cancerous, for the identification of thyroid and colorectal cancers, as now claimed.

Thus, the instant claims are anticiapated by Gould-Rothberg et al.

## Response to Applicants' Arguments

Applicants' arguments presented on 6/28/06 not specifically addressed above are considered to be moot in view of Applicants' amendments to the claims and in view of the new and/or reiterated rejections stated herein, above.

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## Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis V. Wollenberger whose telephone number is 571-272-8144. The examiner can normally be reached on M-F, 8 am to 4:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571)272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <a href="http://pair-direct.uspto.gov">http://pair-direct.uspto.gov</a>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Louis Wollenberger Examiner, Art Unit 1635 August 7, 2006

> SEAN MCGAPRY PRIMARY EXAMINER

> > 1635

# Notice of References Cited Application/Control No. 10/613,105 Examiner Louis V. Wollenberger Applicant(s)/Patent Under Reexamination RASTELLI ET AL. Page 1 of 1

## **U.S. PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	Α	US-6,436,642	08-2002	Gould-Rothberg et al.	435/6
	В	US-			
	С	US-			
	D	US-			
	Ε	US-		,	
	F	US-			
	G	US-			
	Н	US-			
	ı	US-			
	J	US-			
	К	US-			
	L	US-			
	М	US-			

## FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	0					
	Р					
	Q					
	R					
	s					
	т					

## NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	<b>v</b>	rge
	w	
	x	

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).) Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

## 10/613105

# Standard search of SEQ ID NO:2 against the nucleic acid databases

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GenCore version 5.1.9
                   Copyright (c) 1993 - 2006 Biocceleration Ltd.
OM protein - nucleic search, using frame_plus_p2n model
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Run on:
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                                              2301.115 Million cell updates/sec
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score greater than or equal to the score of the result being printed, and is derived by analysis of the total score distribution.

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RESULT 1
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; Patent No. 6500938
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    APPLICANT: Jeffrey J. Seilhamer
     TITLE OF INVENTION: COMPOSITION FOR THE DETECTION OF SIGNALING
     TITLE OF INVENTION: PATHWAY GENE EXPRESSION
     NUMBER OF SEQUENCES: 1490
     CORRESPONDENCE ADDRESS:
      ADDRESSEE: INCYTE PHARMACEUTICALS, INC.
       STREET: 3174 PORTER DRIVE
       CITY: PALO ALTO
       STATE: CALIFORNIA
       COUNTRY: USA
       ZIP: 94304
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       OPERATING SYSTEM: PC-DOS/MS-DOS
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       FILING DATE: HEREWITH
      CLASSIFICATION:
     PRIOR APPLICATION DATA:
      APPLICATION NUMBER:
       FILING DATE:
       CLASSIFICATION:
     ATTORNEY/AGENT INFORMATION:
;
      NAME: Zeller, Karen J.
       REGISTRATION NUMBER: 37,071
       REFERENCE/DOCKET NUMBER: PA-0002 US
     TELECOMMUNICATION INFORMATION:
       TELEPHONE: (650) 855-0555
       TELEFAX: (650) 845-4166
   INFORMATION FOR SEQ ID NO: 1271:
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       STRANDEDNESS: single
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US-09-016-434-1271
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STANDARD SEARCH of SFQ ID. NO: 7

GenCore version 5.1.9

Copyright (c) 1993 - 2006 Biocceleration Ltd.

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July 15, 2006, 10:04:30; Search time 178 Seconds Run on:

(without alignments)

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Pred. No. is the number of results predicted by chance to have a score greater than or equal to the score of the result being printed, and is derived by analysis of the total score distribution.

### SUMMARIES

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## ALIGNMENTS

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RESULT 1
US-09-016-434-1271
; Sequence 1271, Application US/09016434
; Patent No. 6500938
; GENERAL INFORMATION:
     APPLICANT: Janice Au-Young
     APPLICANT: Jeffrey J. Seilhamer
     TITLE OF INVENTION: COMPOSITION FOR THE DETECTION OF SIGNALING TITLE OF INVENTION: PATHWAY GENE EXPRESSION
    NUMBER OF SEQUENCES: 1490
    CORRESPONDENCE ADDRESS:
      ADDRESSEE: INCYTE PHARMACEUTICALS, INC.
       STREET: 3174 PORTER DRIVE
       CITY: PALO ALTO
       STATE: CALIFORNIA
       COUNTRY: USA
       ZIP: 94304
    COMPUTER READABLE FORM:
       MEDIUM TYPE: Floppy disk
       COMPUTER: IBM PC compatible
       OPERATING SYSTEM: PC-DOS/MS-DOS
       SOFTWARE: Word Perfect 6.1 for Windows/MS-DOS 6.2
     CURRENT APPLICATION DATA:
       APPLICATION NUMBER: US/09/016,434
       FILING DATE: HEREWITH
       CLASSIFICATION:
     PRIOR APPLICATION DATA:
```

```
APPLICATION NUMBER:
    FILING DATE:
    CLASSIFICATION:
   ATTORNEY/AGENT INFORMATION:
    NAME: Zeller, Karen J.
    REGISTRATION NUMBER: 37,071
    REFERENCE/DOCKET NUMBER: PA-0002 US
   TELECOMMUNICATION INFORMATION:
    TELEPHONE: (650) 855-0555
    TELEFAX: (650) 845-4166
  INFORMATION FOR SEQ ID NO: 1271:
   SEQUENCE CHARACTERISTICS:
    LENGTH: 594 base pairs
    TYPE: nucleic acid
    STRANDEDNESS: single
    TOPOLOGY: linear
   IMMEDIATE SOURCE:
    LIBRARY: GENBANK
    CLONE: g28638
US-09-016-434-1271
 Query Match
                  100.0%; Score 594; DB 3; Length 594;
 Best Local Similarity 100.0%; Pred. No. 1.5e-183;
                      0; Mismatches
                                     Indels
 Matches 594; Conservative
                                   0;
                                             0: Gaps
                                                     0:
Qу
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Db

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COMMISSIONER FOR PATENTS

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